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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,610	06/01/2001	Glenn McGall	2719.2016-001	1735

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/871,610		MCGALL ET AL.	
	Examiner		Art Unit	
	BJ Forman		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The provisional application upon which priority is claimed provides adequate support under 35 U.S.C. 112 for instant claims 1-15.

Information Disclosure Statement

2. The references listed on the 1449 received 1 June 2001 in Paper No. 8 have been reviewed and considered.

Claim Objections

3. Claim 8 is objected to because "vertices" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 1-15 are indefinite in Claim 1 because the claim is drawn to a method of preparing a nucleic acid array on a support, but the claim does not recite method steps of array preparation and does not result in a nucleic acid array on a support. It is suggested that Claim 1 be amended to recite method steps of array preparation resulting in a nucleic acid array on a support as claimed.

b. Claims 1-15 are indefinite in Claim 1, line 19, for the recitation "the surface of said substrate" because the recitation lack proper antecedent basis in the preceding steps of the claim. Therefore, it is unclear which surface of the support is being referred to. It is suggested that Claim 1 be amended to provide proper antecedent basis and to define a surface of the support.

c. Claims 6 and 7 are each indefinite for the recitation "said interface" because the recitation lacks proper antecedent basis in Claim 1. It is suggested that Claim 6 be amended to provide proper antecedent basis.

d. Claim 8 is indefinite for the recitation "one of the four square vertices" because the recitation lacks proper antecedent basis in Claim 7. It is suggested that Claim 7 or 8 be amended to provide proper antecedent basis.

e. Claims 9-13 are each indefinite for the recitation "nucleic acids are formed on said surface" because "formed" lacks proper antecedent basis in Claim 1. It is suggested that Claim 9-13 be amended to provide proper antecedent basis e.g. replace "formed" with "synthesized".

f. Claims 14 and 15 are each indefinite for the recitation "each different nucleic acid" because the recitation lacks proper antecedent basis in Claim 1 which recites "nucleotide may be the same of different" and "each nucleic acid occupying separate known regions". It is suggested that Claims 14 and 15 be amended to provide proper antecedent basis.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1-6, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Gamble et al (U.S. Patent No. 5,981,733, issued 9 November 1999).

Regarding Claim 1, Gamble et al disclose a method of preparing a nucleic acid array on a support wherein each nucleic acid occupies a separate known region of the support said synthesis comprising: activating a region of the support, attaching a nucleotide to a first region, said nucleotide having a masked reactive site linked to a protective group, repeating steps of activating and attaching on other regions of the support whereby each of said other regions has bound thereto another nucleotide comprising a masked reactive site wherein said another nucleotide may be the same or different from that used in the first step, removing the protecting group from one of the nucleotides bound to one of the regions of the support to provide a region bearing a nucleotide having an unmasked reactive site, binding an additional nucleotide to the nucleotide with an unmasked reactive site, and repeating the steps of removing and binding until a desired plurality of nucleic acids is synthesized, each occupying a separate known region wherein the surface of the substrate is maintained in a position which is vertical or about 30 degrees of vertical and wherein the substrate is rotated around an axis perpendicular to said surface by an amount of from about 20 degrees to about 180 degrees, said rotating being done prior to and subsequent to at least one of said attaching and binding steps (Column 12, line 18-Column 19, line 54 and Claims 9 & 10).

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Regarding Claims 2 & 3, Gamble et al disclose the method wherein said rotating is conducted prior to or subsequent to at least 50% (Claim 2) and at least 80% (Claim 3) of said attaching and binding (Column 12, line 18-Column 19, line 54 and Claim 9).

Regarding Claims 4 & 5, Gamble et al disclose the method wherein said rotating in an amount of from about 70 to about 105 degrees (Claim 4) and of about 90 degrees (Claim 5) (Column 12, line 18-Column 19, line 54 and Fig. 12).

Regarding Claim 6, Gamble et al disclose the method wherein the interface is vertical (i.e. the support is vertical) and said rotating is an amount of about 90 degrees (Column 12, line 18-Column 19, line 54; Claims 9 & 10; and Fig. 12).

Regarding Claim 14, Gamble et al disclose the method wherein each different nucleic acid is in a region having an area of less than about 1 cm² (Column 10, lines 12-15 and Column 12, lines 21-24).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamble et al (U.S. Patent No. 5,981,733, issued 9 November 1999) in view of Bass et al (U.S. Patent No. 6,440,669 B1, filed 10 November 1999).

Regarding Claim 7, Gamble et al teach a method of preparing a nucleic acid array on a support wherein each nucleic acid occupies a separate known region of the support said

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synthesis comprising: activating a region of the support, attaching a nucleotide to a first region, repeating steps of activating and attaching on other regions of the support, removing the protecting group from one of the nucleotides bound to one of the regions of the support, binding an additional nucleotide to the nucleotide with an unmasked reactive site, and repeating the steps of removing and binding until a desired plurality of nucleic acids is synthesized, wherein the substrate is rotated around an axis perpendicular to said surface by an amount of from about 20 degrees to about 180 degrees, said rotating being done prior to and subsequent to at least one of said attaching and binding steps and wherein the substrate is square and a surface of the substrate (i.e. interface) is maintained in a position which is vertical or about 10 degrees of vertical (Column 12, line 18-Column 19, line 54 and Claims 9 & 10) but they do not teach the substrate is substantially square silica chip. However, square planar silica substrates were well known in the art at the time the claimed invention was made as taught by Bass et al (Column 5, lines 38-67) who teach a similar method of preparing a nucleic acid array comprising: activating a region of the support, attaching a nucleotide to a first region, repeating steps of activating and attaching on other regions of the support, removing the protecting group from one of the nucleotides bound to one of the regions of the support, binding an additional nucleotide to the nucleotide with an unmasked reactive site, and repeating the steps of removing and binding until a desired plurality of nucleic acids is synthesized (Column 11, lines 24-64). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the square planar silica substrate of Bass et al to the substrate of Gamble et al based on its well known use as an array substrate and therefore known success as an array substrate for the obvious benefits of obtaining expected results.

Regarding Claim 8, Gamble et al teach the method wherein it is preferable that the substrate be positioned so that the maximal surface area of the substrate is covered by fluid rising from the bottom inlet port (Column 4, lines 21-34) but they do not teach the substrate

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held with one of the four vertices pointing downward. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the position of their substrate such that one of the vertices is pointing downward thereby maximizing the surface area covered by fluid rising across the surface for the obvious benefits of coving the entire surface of the substrate as they desire (Column 4, lines 30-34).

10. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamble et al (U.S. Patent No. 5,981,733, issued 9 November 1999) in view of Brennan (U.S. Patent No. 5,985,551, issued 16 November 1999).

Regarding Claims 9-13, Gamble et al teach a method of preparing a nucleic acid array on a support wherein each nucleic acid occupies a separate known region of the support said synthesis comprising: activating a region of the support, attaching a nucleotide to a first region, repeating steps of activating and attaching on other regions of the support, removing the protecting group from one of the nucleotides bound to one of the regions of the support, binding an additional nucleotide to the nucleotide with an unmasked reactive site, and repeating the steps of removing and binding until a desired plurality of nucleic acids is synthesized, wherein the surface of the substrate is maintained in a position which is vertical or about 30 degrees of vertical and wherein the substrate is rotated around an axis perpendicular to said surface by an amount of from about 20 degrees to about 180 degrees, said rotating being done prior to and subsequent to at least one of said attaching and binding steps (Column 12, line 18-Column 19, line 54 and Claims 9 & 10) and wherein each nucleic

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acid region have center-to-center spacing of 50 microns to 2 millimeters (Column 10, lines 12-15 and Column 12, lines 21-24) but they do not specifically teach the substrate comprises at least 10 different nucleic acids (Claim 9); at least 100 different nucleic acids (Claim 10); at least 1,000 different nucleic acids (Claim 11); at least 10,000 different nucleic acids (Claim 12); at least 100,000 different nucleic acids (Claim 13). However, high density arrays were well known in the art at the time the claimed invention was made as taught by Brennan who teach that there is a need for high density arrays which can be produced rapidly and conveniently (Column 2, lines 1-7). Specifically, Brennan teaches a similar method of preparing a nucleic acid array having regions of 50 microns to 2 millimeters comprising: activating a region of the support, attaching a nucleotide to a first region, repeating steps of activating and attaching on other regions of the support, removing the protecting group from one of the nucleotides bound to one of the regions of the support, binding an additional nucleotide to the nucleotide with an unmasked reactive site, and repeating the steps of removing and binding until a desired plurality of nucleic acids is synthesized wherein the array comprising at least 100,000 regions of 50 microns to 2 millimeters (Column 2, lines 17-19 and Example 2, Column 7, line 36-Column 8, line 10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the high density array teaching of Brennan to the array of Gamble et al and to form at least 10; at least 100; at least 1,000; at least 1,000, at least 100,000 different nucleic acids on the surface based on the teaching of Brennan wherein methods for producing high density arrays rapidly, conveniently and accurately is needed and desired (Column 2, lines 1-7). Therefore, it would have been obvious to one skilled in the art to modify method of making arrays of Gamble et al by producing high density arrays for the expected benefits of speed, convenience and accuracy as taught by Brennan (Column 2, lines 1-7).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
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September 23, 2002